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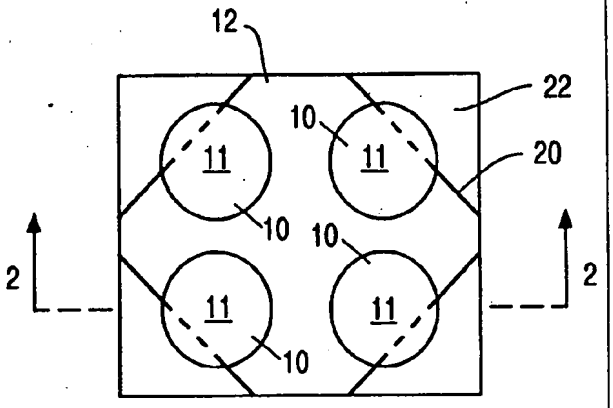
(54) Title: TRANSDERMAL DELIVERY SYSTEM PACKAGE

(57) Abstract

This invention is a new packaging system for transdermal devices (10). In the preferred embodiment, the devices are adhesive patches mounted on a release liner (12). The liner surface is chosen so that it will not adhere to the adhesive on the devices. Rather, the devices may be peeled off easily by the user. The release liner (12) is preferably perforated (20) or scored to permit a portion (22) of the liner below each device to be torn off by the user. The device may be lifted from the liner by using the torn off portion as a handle. The torn off portion of the liner is itself removed from the device only after the uncovered portion of the device is applied to the user's skin.



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TRANSDERMAL DELIVERY SYSTEM PACKAGE

Background of the Invention

This invention relates generally to a package for a transdermal delivery system and, in particular, to a release liner and pouch for use with multiple transdermal delivery systems.

Transdermal delivery systems deliver substances to a user's tissues and/or blood stream through the user's skin. Examples are NICOTROL® nicotine transdermal systems and MINITRAN® nitroglycerin transdermal systems, both available from Cygnus Therapeutic Systems. Such systems are typically formed as a flexible patch containing the substance within a reservoir. The patch attaches to the user with adhesive. Contact between the patch's active face and the user's skin permits the substance to transfer from the reservoir to the user at a rate determined in part by the construction of the patch and in part by the nature of the substance.

The substance within the transdermal delivery system may be adversely affected by contact with light, water, air, or airborne substances. Packaging must be provided, therefore, to prevent loss or degradation of the substance within the system's reservoir. One prior art packaging approach is described in U.S. Patent No. 5,077,104.

Transdermal delivery systems may be provided to the user with adhesive already applied to the delivery side of the patch. The system's packaging must therefore also prevent degradation of the adhesive and inadvertent attachment of the patch to the wrong object. Transdermal

delivery systems are therefore typically releasably mounted on liners, as shown in U.S. Patent No. 4,915,102 and European Patent Application No. 401 949.

One prior art way of facilitating the handling and attachment adhesive patch drug delivery systems was to provide a cut in the patch's release liner (such as an "S" cut, a straight cut, etc.) to make the removal of the release liner easier. Similarly, another prior art approach was to make the release liner larger than the patch, such as by providing an extending tab. Both approaches, however, require some finger contact with the adhesive/drug surface.

To ensure that the substance within the transdermal delivery system reservoir is delivered only to the desired application site on the user, and to avoid contamination or degradation of the adhesive surface (especially for multiple-day wear), it may be desirable to provide a way for the user to apply the system without coming in contact with the patch's adhesive delivery surface. One approach to this problem is shown by some prior art bandage products in which one part of a multiple-part release liner may be removed from a portion of the adhesive surface. The remaining portion of the release liner is removed only after the earlier-exposed portion of the adhesive surface has been attached to the patient.

Finally, transdermal delivery systems have a limited life, and multiple systems may be needed by a single user to accomplish the purpose for which the system was prescribed. What is needed, therefore, is a way to package multiple transdermal delivery systems together.

Summary of the Invention

This invention meets these and other needs by providing a new packaging system for transdermal devices. In the preferred embodiment, the devices are adhesive patches mounted on a release liner. The liner surface is chosen so that it will not adhere to the adhesive on the devices. Rather, the devices may be peeled off easily by the user.

The release liner is preferably perforated or scored to permit a portion of the liner below each device to be torn off by the user. The device may be lifted from the liner by the torn-off portion. The torn-off portion of the liner is itself removed from the device only after the uncovered portion of the device is applied to the user's skin.

Brief Description of the Drawings

Figure 1(a) is a top elevational view of the transdermal delivery system package of this invention designed to hold multiple transdermal delivery systems.

Figure 1(b) is a top elevational view of the transdermal delivery system package of this invention designed to hold a single transdermal delivery system.

Figure 2 is a side cross-sectional view of the preferred embodiment of this invention.

Figure 3(a) is a top elevational view of a single transdermal delivery system showing how the package may be used to apply the system.

Figure 3(b) is a bottom elevational view of the single transdermal system of Figure 3(a).

Detailed Description of the Preferred Embodiments

This invention provides a system for mounting and storing single or multiple transdermal delivery devices. A preferred embodiment of the invention is

shown in Figures 1-3. Transdermal delivery devices 10 are mounted on a release liner 12 so that the devices' substance delivery surfaces 13 face toward liner 12 and the devices' top protective surface 11 face award from liner 12. In the preferred embodiment, release liner 12 is made from polyester, polyethylene, polystyrene, polycarbonate or paper coated with silicone or a fluorochemical compound, or a combination of these materials.

As shown in Figure 2, devices 10 each have an internal reservoir layer 14, a bottom adhesive layer 15, and a top protective layer 16 in a manner known in the art. Devices 10 and liner 12 are preferably stored in an air-tight, resealable bag 18 made of a plastic film or a foil laminate. Bag 18 may include a plastic zipper or zip-lock mechanism 19. Bag 18 may also include a non-resealable seal mechanism (not shown) that must be unsealed by the user the first time the package is opened.

Liner 12 has scores or perforations 20 that permit portions 22 of the liner to be torn away from liner 12. Perforations 20 run beneath a portion of each device 10, as shown in Figure 1. At least part of each liner portion 22 is not covered by a device 10.

In use, the devices and release liner are removed from the resealable bag. A single device may be removed from the release liner by tearing liner 12 along one of the perforated lines 20, and lifting the device 10 off the liner 12 with the torn-off portion 22. As seen in Figure 3, torn-off portion 22 provides a means for the user to hold device 10 without actually coming into contact with the device. The portion of device 10 not covering torn-off portion 22 may be placed at, and adhered to, the chosen site on the user's skin. Thereafter, torn-off portion 22 may be removed, and the

remaining portion of device 10 may be adhered to the user's skin.

If any unused devices 10 remain on the release liner, the liner and devices may be placed back inside bag 18, and the bag may be resealed.

Examples of transdermal delivery systems that may be used with the package of this invention include systems delivering natural or synthetic estrogens, progestins, or combinations of the two; systems delivering anti-hypertensives for high blood pressure; systems delivering nitroglycerin; and systems delivering nicotine compounds. Modifications to the invention may be made without departing from the scope of the invention. For example, other shapes and configurations of the entire release liner and of the removable portion of the release liner may be used.

We claim:

1. A mounting system for a transdermal device comprising: a release liner, the release liner having means for removing a first portion of the release liner from a second portion of the release liner, and means on the release liner for releasably receiving an adhesive-backed transdermal device so that a first portion of the transdermal device is removably mounted on the first portion of the release liner and a second portion of the transdermal device is removably mounted on the second portion of the release liner.

2. The mounting system of claim 1 wherein the means for removing a first portion of the release liner comprises means for separating the first portion of the release liner from the second portion of the release liner along a predetermined line.

3. The mounting system of claim 2 wherein the means for separating comprises a perforation formed in the release liner along the predetermined line.

4. The mounting system of claim 1 further comprising handle means for holding the second portion of the release liner when the first portion of the release liner has been separated therefrom.

5. The mounting system of claim 4 wherein the handle means comprises an area on the second portion of the release liner that remains uncovered when the transdermal device is mounted thereon.

6. A transdermal delivery device package comprising: a first transdermal delivery device

removably mounted on a release liner, a first portion of the first transdermal delivery device covering a first portion of the release liner and a second portion of the first transdermal delivery device covering a second portion of the release liner; and means for separating the first portion of the release liner from the second portion of the release liner.

7. The package of claim 6 further comprising a second transdermal delivery device removably mounted on the release liner, a first portion of the second transdermal device covering a third portion of the release liner and a second portion of the transdermal delivery device covering a fourth portion of the release liner; and means for separating the third portion of the release liner from the fourth portion of the release liner.

8. The package of claim 6 further comprising a resealable pouch adapted to contain the transdermal delivery device and the release liner.

9. A method for applying a transdermal delivery device to a site on a user comprising the following steps: providing a transdermal delivery device having an active face mounted on a release liner; separating a first portion of the release liner from the transdermal device to expose a first portion of the active face of the transdermal device while leaving a second portion of the active face of the transdermal device mounted on a second portion of the release liner; attaching the first portion of the active face of the transdermal device to the site on the user; separating the second portion of the release liner from the second portion of the active face of the transdermal device; and

attaching the second portion of the active face of the transdermal device to the site on the user.

10. A method of packaging transdermal devices comprising the following steps: providing a release liner having a surface from which the transdermal devices can be removed; forming means for separating a first portion of the release liner from a second portion of the release liner; mounting a transdermal delivery device on the release liner so that a first portion of the transdermal delivery device is mounted on the first portion of the release liner and a second portion of the transdermal delivery device is mounted on the second portion of the release liner.

11. The method of claim 10 wherein the forming step comprises forming means for separating the first portion of the release liner from the second portion of the release liner along a predetermined line.

12. The method of claim 10 further comprising the steps of forming means for separating a third portion of the release liner from a fourth portion of the release liner; mounting a second transdermal delivery device on the release liner so that a first portion of the second transdermal delivery device is mounted on the third portion of the release liner and a second portion of the second transdermal delivery device is mounted on the fourth portion of the release liner.

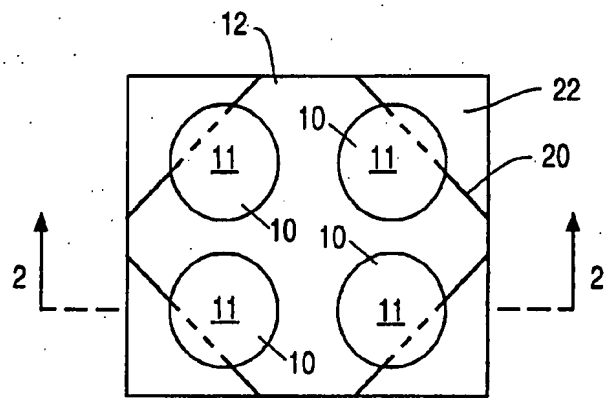

FIG. 1(a)

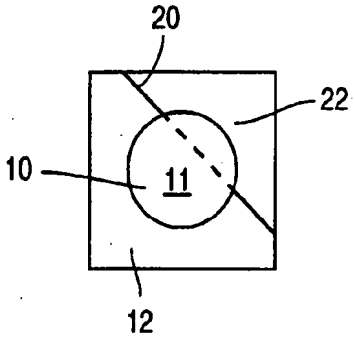

FIG. 1(b)

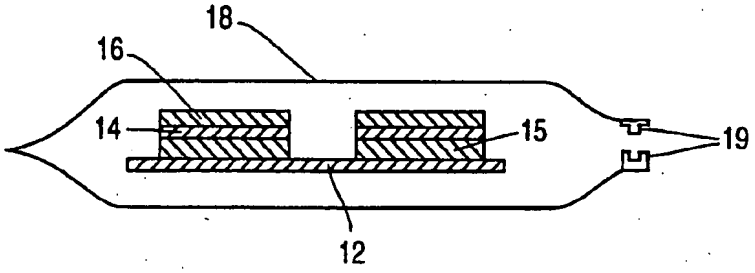

FIG. 2

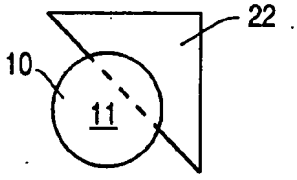

FIG. 3(a)

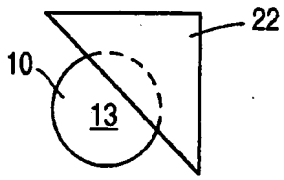

FIG. 3(b)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/06681

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61K 9/22
US CL :604/890.1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 206/440-442, 484; 602/48-52, 57, 59; 604/289, 290, 304, 307, 890.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,064,422, (WICK), 12 November 1991. See entire document.	1, 2, 4-7, 9-12 --- 3, 8
Y	US, A, 2,358,246, (C. NICOLLE), 12 September 1944. See entire document.	3
Y	US, A, 3,247,957, (M. S. KEMBLE), 26 April 1966. See entire document.	8
A	US, A. 4,666,441, (ANDRIOLA ET AL.), 19 May 1987. See entire document.	1-12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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